K111439

AUG 24 2011

510(k) Summary
Chesapeake Spinal System
K2M, Inc.

This 510(k) summary for the Chesapeake Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Date Prepared: 08/23/11

Contact Person :
Nancy Giezen
K2M, Inc.
Telephone: 703-777-3155

2. Tradename:	Chesapeake Spinal System
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device with Bone Graft, cervical
Device Product Code:	OVE
Regulation Number:	888.3080
Regulatory Class:	Class II

3. Predicate or legally marketed devices which are substantially equivalent :

- K2M Chesapeake (K092211)
- K2M Aleutian (K051454, K082698)
- Surgicraft Stalif C (K072415)
- Globus Coalition (K083389)
- Cardinal Spine STCC (K100698)

4. Description of the device:

The Chesapeake Spinal System consists of interbody implants and titanium bone screws intended for fusion, without the need for supplementary fixation. The implants are hollow tube structures that can be packed with bone graft and allow for passage of screws for fixation to the vertebral body. Multiple sizes of implants are available to accommodate anatomical variations.

Materials: The cervical interbody implants are made of CP titanium and the screws are fabricated from Ti6Al4V titanium, in accordance with ASTM F67 and F1472

Function: The system functions as an intervertebral body fusion device to provide support and stabilization of the cervical segments of the spine.

5. Intended Use:

The Chesapeake Spinal System is intended to be used with the bone screws provided and requires no additional supplementary fixation.

When used as a cervical intervertebral body fusion device, the Chesapeake implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The Chesapeake cervical implants were mechanically tested and compared to predicate devices. The Chesapeake Spinal System performed equally to or better than these systems in static compression, static torsion, dynamic compression, dynamic torsion and expulsion in accordance with ASTM F2077 and F2267. The design features and sizing of the components were also compared and the Chesapeake Spinal System was found to be substantially the same as these systems.

There are no significant differences between the K2M implants and other wires currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

K2M, Inc.
% Ms. Nancy Giezen
751 Miller Drive SE, Suite F1
Leesburg, Virginia 20175

AUG 24 2011

Re: K111439
Trade/Device Name: Chesapeake Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: August 05, 2011
Received: August 08, 2011

Dear Ms.Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K111439

Device Name : **Chesapeake Spinal System**

Indications For Use :

The Chesapeake Spinal System is intended to be used with the bone screws provided and requires no additional supplementary fixation.

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Prescription use __X__ OR Over-the-counter use _____
(PER 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111439